

An Open- Label Single Arm Clinical Study To Evaluate Effectiveness Of Kandughna Mahakashaya (Of Charaka Samhita) In Yoni Kandu (Pruritus Vulvae)

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ABSTRACT: Diseases are the consequence of consumption of various nidanas that are mentioned for the same in the ayurveda classics. Amongst, Shareerika mithyayoga is also one such hetu for disease, where Kandu is considered, with this note the incidence of Pruritic vulvae with prevalence rate of 16% population in women suffers from same. Henceforth, the Yonikandu was considered for the present study i.e., retrospective evaluation of the Kandu through systematically developed scale in the subjects suffering from Yonikandu. Henceforth, the Yonikandu was considered for the present study i.e., retrospective evaluation of the Kandu through systematically developed scale in the subjects suffering from Yonikandu. Once the Kandu severity assessment is done, the treatment also follows the lines of Kandughna Chikitsa i.e., intervention by the Kandughna Mahakashaya(of Charaka Samhita) Kwatha and Malahara to evaluate its efficacy.

Keywords- Kandughna, Kandughna Mahakashaya, Yonikandu, Pruritic vulvae, Kandughna Mahakashaya Kwatha, Kandughna Mahakashaya Malahara,

I. INTRODUCTION

Approximately 16% of female population presents with vulvar itching which is not a disease always, even symptoms in many diseases which affects quality of life. Maintaining reproductive health and hygiene is the prime focus in females who are easily susceptible for infection which may deteriorate health. Even Ayurveda classics have signified importance of Stree by stating as source for Dharma(righteousness), Artha (wealth), Lakshmi (prosperity)and Apatya (progeny).

Considering so far mentioned situations and problems to seek solution Bheshaja Chatuska is selected from Sutrasthana. Because, "Shlokasthan Samuddhistam Tantrasaasya prayojanam" (Shlokastana plays prime role in Swasthysa Swastha Rakshana and Athurasya Vikara

Prashamana), Shatvirechanashatashreetiya last Adhyaaya of Bheshaja Chatuska emphasis on Antahparimarjana and Bahirparimarjana Chikitsa. Kandughna Mahakashaya one among Dashemani seems to be applicable and appropriate in current study.

With reference to above all factors, the Kandughna Mahakashaya was selected. So, the study aims evaluation of Kandughna mahakashaya in Yonikandu roga with the null hypothesis (H₀): **Kandughna mahakashaya has no effect in Yoni kandu (Pruritic vulvae)** & the alternative hypothesis(H₁) i.e, **Kandughna mahakashaya is effective in Yonikandu (Pruritic vulvae).**

II. MATERIALS & METHODS

SOURCE OF DATA

Female subjects (age group 18years – 70 years) irrespective of caste, religion, occupation, Socio-economic status, attended OPD and IPD of Government Ayurveda Medical College, Mysuru & Government Hi-tech Panchakarma hospital, Brindavan extension Mysuru and meeting all the inclusion criteria were recruited in the study. Precautions were taken not to include subjects meeting exclusion criteria.

Drug Sample: Kandughna Mahakashaya dashemani dravyas as mentioned in Charaka Samhita i.e., Chandana, Nalada, Krutamala, Naktamala, Nimba, Kutaja, Sarshapa, Madhuka, Daruharidra & Musta which were authenticated by Indian pharmacopeia were selected & prepared Kwatha Churna & Malahara from B V Pandits 'The Sadvaidyasala Private Limited,' Nanjangudu, Mysuru & the same GMP certified Medicine was utilized for study. **Drug form:** ▪ Kandughna Mahakashaya – For internal administration. 1. Drug formulation – Kashaya All ten drugs (Rakta Chandana as Chandana) were taken in equal quantity were crushed to a coarse powder. The same samples were given to subjects for preparation of Qwatha in classical method.

For external application – Malahara Method of preparation – Kalka – 1 part, Tila taila – 4 parts, Kandughna Kashaya – 16 parts Kandughna Mahakashaya drugs were used for kalka and Kashaya preparation. According to taila paka vidhi, taila was prepared. After preparation of taila, Madhuchista was added in 1: 6 ratios to convert it into malahara form. Then it was packed into airtight tube.

DIAGNOSTIC CRITERIA

Based on 2021 ICD -10 CM Diagnostic CODE L29.2 –

- Female subjects complaining pruritis vulvae as a cardinal symptom acute or chronic \leq 6weeks with or without vaginal discharge.
- An intense itching sensation at female external genitals that produces the urge to rub or scratch the skin to obtain relief or irritation that makes to scratch itchy area.
- Total white blood cells count less than 16,000cells/mm, vaginal pH \leq 6.

INTERVENTION

Drug form	Kandughna Mahakashaya – Kashaya	Kandughna Mahakashaya – Malahara
Dose	80 ml Kashaya divided into two doses in a day (40ml Kashaya for one time	12gms of Malahara with applicator is used for vaginal or vulvar application once in a day.
Mode of Administration	Orally	Local Application
Anupana	Sukhoshna Jala	-
Time of Administration	After food	After bath, drying external genitals with clean cloth followed by malahara should be applied using applicator.
Duration	7 days	7 days

Subjects were given Kwatha-15gms of Kandughna Mahakashaya Stoola(coarse) Qwatha Churna was taken in chemically inert and clean stainless – steel vessel, 16 parts of clean water i.e., 240 ml of water is added to vessel placed over mild fire, boiled and water reduced to 80ml. This was taken by subjects in two equally divided doses.

- Kandughna Malahara tube is provided with vaginal applicator, married women were instructed to use Malahara after hygienic clean of hands and genitals, removed excess moisture with cotton swab or clean cotton cloth. Malahara application method • The applicator is an empty plastic tube called a barrel.

INCLUSION CRITERIA

- Female subjects aged between 18years to 70 years irrespective of caste, occupation, marital status, socio-economic status with itching in vulvar or vaginal region were selected for study.
- Female subjects complaining vulvar-vaginal itching as a cardinal symptom with or without vaginal discharge \leq six weeks
- Vulvar or vaginal itching induced by life style disorders like diagnosed Diabetes mellitus and obesity.

EXCLUSION CRITERIA

Vaginal or vulvar itching induced by:

- Pregnancy and lactational period.
- Intrauterine contraceptive devices

STUDY DESIGN - Purposive Sampling method with pre-post treatment assessments.

PLAN OF STUDY

Sample size – 45

Study duration – 7 days.

- Subjects were instructed for hygienic hands and genitals prior to application of malahara. Time of Administration After food After bath, drying external genitals with clean cloth followed by malahara should be applied using applicator.

Remove the cap from the end of the tube, screw the open end of the applicator onto the tube of malahara. One should make sure applicator is tightly held with tube end.

- Squeeze the tube and fill the applicator until it is full.

• To use applicator, subject should lie on their back with their knees drawn up toward chest. Hold the applicator by the end of tube and gently insert into

the vagina as far as it will comfortably go. Slowly press the tube to release the malahara into the vagina.

- After using, pull the applicator completely out of vagina with tube and wash the applicator with

lukewarm, soapy water and dry thoroughly. In case of unmarried female, malahara was instructed to apply on vulvar region with hygienic hands and rest for one hour and thereby can be swiped with clean cotton swab.

ASSESSMENT CRITERIA

Subjects were assessed using the Vaginitis scale

ASSESSMENT CRITERIA	
Sl. No	Factors for assessment
Q1-	Objective parameters Vaginal itching associated with Discharge . No - 1 a. Yes, no need to change inner garments- 2 b. Yes, need to change inner garments twice a day - 3 c. Yes, need to use sanitary pads – 4
Q2	Do vaginal discharge associate with odour? . No – 1 a. Yes, non -offensive – 2 b. Yes, offensive - 3 c. Fishy odour – 4
Q3	Consistency of vaginal discharge . Watery -1 a. Thin -2 b. Thick – 3
Q4.	Oedematous appearance . No – 1 a. Mild reddish discoloration - 2 b. Reddish discoloration with oedema of vulva & vagina – 3
Q5.	Subjective parameter Low back pain . Absent – 1 a. Mild – 2 b. Moderate- 3 c. Severe -4
Q6.	Burning sensation of vulvo-vaginal region . No – 1 a. Yes, mild – 2 b. Yes, moderate – 3 c. Yes, severe – 4
Q7	Early fatigue . No – 1 a. Yes, mild – 2 b. Yes, moderate – 3 c. Yes, severe – 4

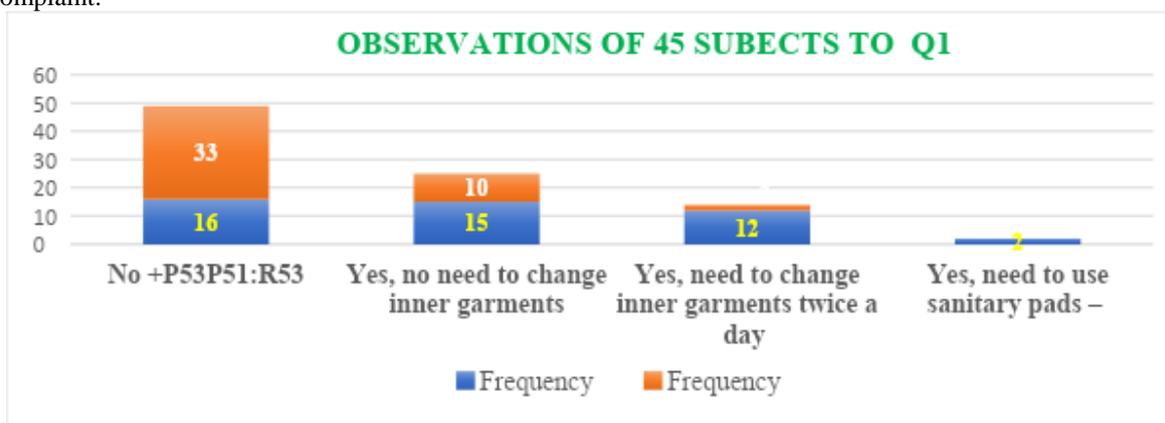
OBJECTIVE PARAMETER

- Hb%
- Total White blood cells & Differential count
- Urine routine and microscopic
- Vaginal pH
- Fasting Blood Sugar & Post-Prandial Blood sugar
- Culture of the vaginal secretions, pap smear if necessary to rule out other pathologies.

III. OBSERVATIONS

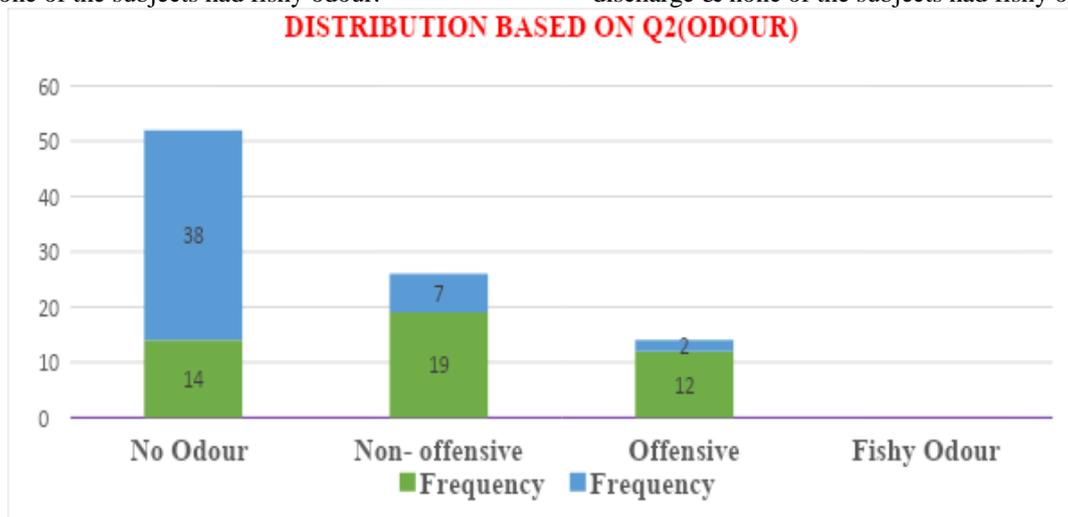
Before intervention, maximum 16 subjects (35.6%) had no complaint of vaginal white discharge, 15 subjects (33.33%) presented with vaginal white discharge but no need to change inner garments, 12 subjects (26.66%) need to change inner garments twice a day, none of the subjects reported of using sanitary pads for same complaint.

After intervention, maximum 33 subjects (74.44%) had no complaint of vaginal white discharge, 10 subjects (22.22%) presented with vaginal white discharge but no need to change inner garments, 2 subjects (4.44%) need to change inner garments twice a day, none of the subjects reported of using sanitary pads for same complaint.



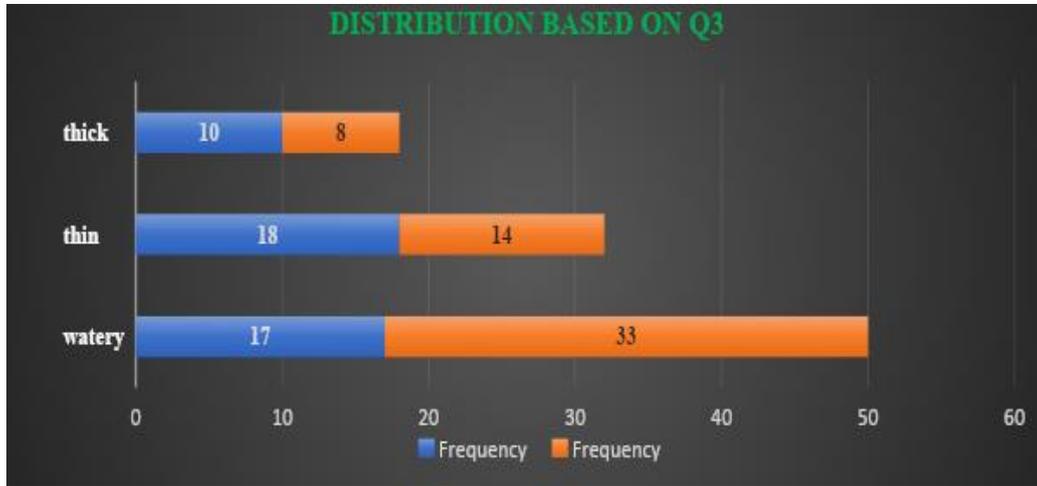
Before intervention, 14 subjects (31.1%) had no odour of vaginal discharge, 19 subjects (37.8%) had non-offensive odour, 12 subjects (26.7%) had offensive odour of vaginal discharge and none of the subjects had fishy odour.

After intervention, 38 subjects (84.4%) had no odour of vaginal discharge, 7 subjects (15.5%) had non-offensive odour of vaginal discharge, 2 subjects (4.44%) had offensive odour of vaginal discharge & none of the subjects had fishy odour.



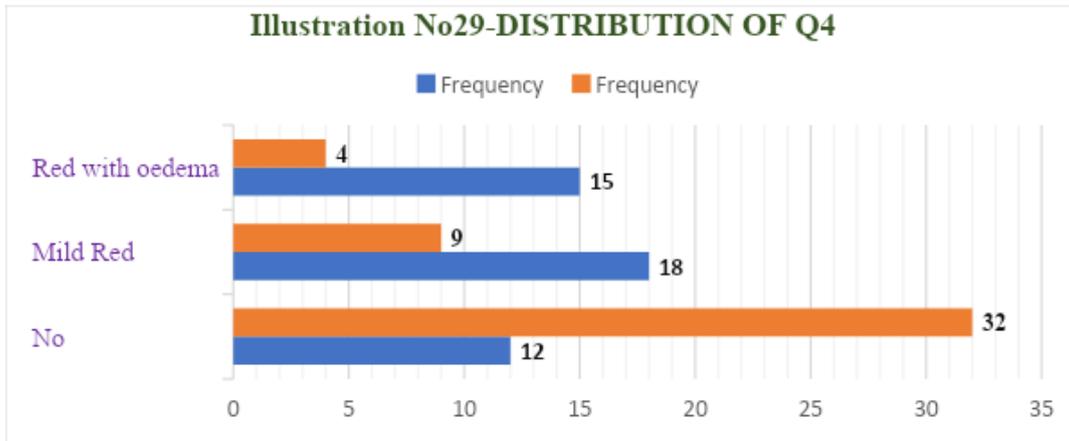
Before intervention, 17 subjects (37.8%) had watery consistency of vaginal discharge, 18 subjects (40%) had thin consistency & 10 subjects (22.22%) had thick consistency of

vaginal discharge. After intervention, 33 subjects (73.33%) had watery consistency of vaginal discharge, 14 subjects (31.33%) had thin consistency & 8 subjects (17.78%) had thick consistency of vaginal discharge.



Before intervention, on examination 12subjects (32%) had no redness & oedema of vulvae, 18 subjects (40%) had mild redness, 15 subjects (33.33%) had redness with oedema in vulvar region. After intervention, on examination

32 subjects (71.1%) had no redness and oedema of vulvae, 9 subjects (20%) had mild redness, 4 subjects (8.88%) had redness with oedema in vulvar region.



Before intervention, 14subjects (31.1%) had no low back pain, 19subjects had mild low back pain, 12subjects (26.6%) had moderate low back pain. After intervention, 26subjects (57.78%) had no low back pain, 16subjects (35.5%) had mild & 3subjects (6.67%) had moderate low back ache.

After intervention, 23 subjects (51.2%) no burning sensation in vulvar region, 12subjects had mild & 10 subjects (22.2%) had moderate burning sensation in vulvar region.

Before intervention, 24subjects (53.33%) had no burning sensation in vulvar region, 9 subjects (20%) had mild & 12 subjects (33.33%) had moderate burning sensation at vulvar region.

Before intervention, maximum 28subjects (62.22%) had no early fatigue,12subjects (26.67%) had mild & 5subjects (11.12%) had moderate fatigue. After intervention, 30 subjects (66.67%) had no early fatigue, 12 subjects (26.67%) had mild fatigue & 3subjects (6.67%) had moderate fatigue.



RESULTS OF Paired Samples test on haemoglobin -percentage, fasting blood glucose level & post prandial blood glucose level.

	Paired Differences	T	Df	Sig. (2-tailed)	
					Mean
Pair 1 HB_BT - HB_AT	.06000	.23587	1.706	44	.095
Pair 2 FBS_BT - FBS_AT	4.28889	7.03440	4.090	44	.000
Pair 3 PPBS_BT - PPBS_AT	9.11111	9.19541	6.647	44	.000

Paired Samples Test on vaginal pH, uwc,uec

	Paired Differences	t	Df	Sig. (2-tailed)	
					Mean
Pair 1 pH_BT - pH_AT	.15556	.16653	2.847	44	.856
Pair 2 ESR_BT - ESR_AT	.42222	1.33976	2.114	44	.040
Pair 3 TC_BT - TC_AT	251.11111	494.80126	3.404	44	.001

OVERALL ASSESSMENT OF THE RESULTS

Table no- Observation on overall scores & grades			
Scores	Grading	Frequency BT	Frequency AT
7-11.5	Minimal severity	4	28
11.6- 17	Mild severity	21	11
17.5 -23	Moderate severe	20	6
≥23.5	Adversely severe	0	0

IV. DISCUSSION

In most of the cases pruritus & vaginal discharge goes hand in hand. The pradhanata of Kapha is signified & also the drava rupa of Pitta. After treatment, maximum number of subjects had no complaint of vaginal discharge signifies the mode of action of dravyas in terms of Tikta & Kashaya rasa. Laghu & ruksha is predominant in Kandughna, reduces both Pitta & Kapha. The gana contains both sheeta & ushna pradhana dravyas, even they own same effect.

The maximum subjects were of non-offensive odor which suggestive of Pitta pradhana saama lakshana, here Gandha is again pitta paka lakshana. After treatment maximum subjects had no odor complaints which suggestive of pitta niraama lakshana. The Gana is rich in Deepana & pachana dravyas which did Amahara & resulted in no odor.

The maximum subjects were of thin watery discharge which is indicative of mild niraama pitta lakshana & Vata pradhanata. 17 subjects (37.8%) had watery consistency of vaginal discharge suggests of Vata pradhanata. After treatment, maximum 33 (73.33%) subjects had watery consistency which suggestive of Vata niraama lakshana. The Tikta- Kashaya with laghu - ruksha guna is Vatakara. So, balancing the dosha combination is the phenomenon.

The maximum 15 subjects (33.33%) of were examined of redness & oedema of vulva which suggestive of Pitta pradhanata as Paka is the lakshana of pitta dosha. After treatment, 32 subjects ((71.1%) had no redness or oedema which suggestive of Pitta shamana chikitsa as Madhu chista as vyadhi pratyanka action of vrana ropana & visarpahara, dosha pratyanka action like Mridu, Snigdha.

The maximum of 14 subjects (31.1%) had did not present with low back ache suggestive the infection had not spread to cervix, endometriosis & other uterus organs. The yonikandu seems to Stanika lakshana & most of them did not present with Vata pradhana lakshana. But, 26 subjects (31.1%) did not present with mild low back pain (may be due other cause) had reduced suggestive of reduction of pain from mild to no pain.

The maximum of 24 subjects (53.3%) had burning of vulvar region suggestive of Ushna guna pradhana-Saama pitta prakopa & after treatment maximum 23 subjects (51.2%) subjects persist with burning suggestive of bhooyaso alpa avajeyate nyaya which describes, out of ten dravyas, only

four dravya possess Ushna veerya, hence the action of ushna guna with relation to laghu & ruksha (acting as supporting agent) is intense in present scenario & lead to result.

The maximum of 28 subjects (62.1%) had no fatigue, 12 subjects had mild fatigue & after treatment there is no evident changes in fatigue suggestive of the dravyas do not possess balya or shramahara action, as most of them possess langhaneeya karma.

The fasting blood glucose level & post prandial blood glucose level before & after intervention results with high significant value of 0.001, as many of the Dravya possess Tikta-Kashaya rasa results in Kapha kshaya & relieves from Rasa- Medo-Mamasa dusti. Prameha one of the santarpanjanya vyadhi, the mode of action of dravya may be vyadhi pratyanka & Dosha pratyanka also.

The vaginal pH & ESR was not influenced by intervention.

The total white blood cells count had significant value of .001, which signifies the removal of infectious & inflammatory agents. It also signifies Amahara action like Pachana & Srotoshodhana.

The result of intervention with urine epithelial count & urine white blood cells count had significant value of .003, which was moderately significant, which signifies the Malashodhana & Amahara action of dravyas.

The word Kandughna, it is derived from kandu hanti iti which means pacifying the pruritus/itch. Based on commentators, it reveals that those dravyas which have the capacity to destroy the disease condition, The kandughna mahakashya mentioned denotes its lakshanika chikitsa or the transient effect of dravya.

Considering the nature of Kandu Lakshana & vyadhi, it is said as Santarpanotta & rakta pradoshaja vyadhi. The pathology mainly involving is Kapha- pitta & rakta as Dushya. So, one can infer that the drugs of ghna shatkah chiefly perform **Apatarpana karma – Shamana karma. kandughna perform apatarpana**, where there are other category of **chikitsa principles**, an attempt is made to correlate the **kandughna with chikitsa krama**.

V. CONCLUSION

The Yonikandu is lakshana in Yoniroga which is Kaphapradhana vyadhi with anubandha of

pitta & vata. The rasavaha & rakta vaha srotodusti leads to Yonikandu.

The efficacy of Kandughna mahakashaya dravyas in the context of Yonikandu was established & based on observations & results, it was inferred that Kandughna mahakashaya is more effective in Kapha Pradoshaja avastha with significant value.001

The intervention of Kandughna kashaya & malahara was effective in yoni srava, gandha, kleda, paaka & shotha of yoniroga, but not effective in Yonidaha.

Kandughna action can be defined as Dravyabhuta, Apatarpana, Shamana, Yuktivypashraya, Langhaneeya, rukshaneeya karma & kapha dosha pratyanka chikitsa.

Kandughna Mahakashaya provide a transient cure in any type of Yoni Kandu. Henceforth, it is mandatory formulation for practitioners.

The null hypothesis(H₀) – Kandughna mahakashya has no effect in Yoni kandu(Pruritic vulvae) was rejected & the alternative hypothesis i.e, Kandughna mahakashya is effective in Yonikandu

VI. SUMMARY

The applied study aims at evaluation of Kandughna Mahakashaya in Yonikandu (Pruritic Vulvae). Establishing the relation of efficacy was achieved by random sampling & purposive sampling followed by assessment of severity of Kandu through systematically developed Kandu Assessment scale. All the 45 subjects were grouped into single group and baseline assessment was done with pruritic scale and Kandu assessment scale. The Kandughna Mahakashaya kwatha & Kandughna Mahakashaya Malahara were administered as intervention as the study was single arm, open labelled, non-comparitive, efficacy evaluation trial. The subjects were assessed after an intervention of seven days with pruritic scale.

The intervention of Kandughna mahakashaya Kwatha and Malahara was statistically highly significant with p value .001. The intervention was also found to be effective on all parameters of Yonikandu(Pruritic vulvae).

The efficacy of Kandughna Mahakashaya Kwatha & Malahara in the context of Yonikandu(Pruritic vulvae) was established and based on observations and clinical results, it is inferred that Kandughna Mahakashaya is more effective in Kapha pradhana avastha of Vyadhi.

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